9600 Aldrich Avenue South

Telephone 612-884-4051

Minneapolis, Minnesota 55420 USA



510(K) SUMMARY

Trade Name:

Telex Select 2-40 with Adaptive Compression®

Common Name:

FM at-the-ear Auditory Trainer

Classification Name: Hearing Aid, Group and Auditory Trainer, 77EPF

Phonic Ear PE700 Free Ear Auditory Trainer, or

Equivalent to:

AVR/Sonovation Extend Ear, or Telex Model TDR-7AA K913495 Fax 612-884-0043

Description:

Intended use:

to amplify and transmit sound to the ear.

Features:

Adaptive Compression; True FM Override (patent pending); two channel

switch selectable receiver (patent pending); user replaceable channel crystals (patent pending); function switch allows hearing aid only, FM

reception only, or both;

Assembly:

assembled from standard components that are widely used by other

hearing aid manufacturers.

Technical characteristics: technical specifications comply with S3.2-1987 ANSI standards.

Fit:

frequency response per S3.2-1987 ANSI standard as shown on

specification filed with 510(k).

Controls:

Volume control, Mode Switch, Channel Selector Switch, Audiological

Controls (output, gain, and tone).

Power:

Standard hearing aid battery (675)

Comparison to predicate device: identical to the Phonic Ear PE700, except for two channel

switch selectable FM reception, user replaceable channel crystals, and an

additional audiological control (gain).

Submitted by:

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